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FULBRIGHT & JAWORSKI, LLP
1301 MCKINNEY
SUITE 5100
HOUSTON, TX 77010-3095

EXAMINER

BARTON, JEFFREY THOMAS

ART UNIT	PAPER NUMBER
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1753

DATE MAILED: 09/23/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/069,827	Applicant(s) DERAND ET AL.	
	Examiner Jeffrey T. Barton	Art Unit 1753	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 August 2002.
 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-41 is/are pending in the application.
 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
 5) ☐ Claim(s) _____ is/are allowed.
 6) ☒ Claim(s) 1-41 is/are rejected.
 7) ☐ Claim(s) _____ is/are objected to.
 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☒ All b) ☐ Some * c) ☐ None of:
 1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input checked="" type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. <u>20040909</u> . |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>20020814, 20020226</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Specification

1. The disclosure is objected to because of the following informalities: on page 7, at line 4, the upper limit of the preferable molecular weight range is given as "2000,000", while it appears that "200,000" was intended.

Appropriate correction is required.

Claim Objections

2. Claims 2 and 22 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. These claims specify that the material and polymer, respectively, are "organic or inorganic". There is no material or polymer that would fall outside this group, and thus this does not constitute a further limitation.

3. Claims 11, 13, 19, 33, and 35 are objected to because of the following informalities:

a. In claim 11, the items listed in the Markush group are not types of polymers. Various polymers may contain hydroxyl groups, ethylene oxy groups, or amide groups, but they are not polymers in and of themselves. The claim is

treated herein as requiring a polymer that contains hydroxyl groups, ethylene oxy groups, or amide groups.

b. In claim 13, line 2, instead of stating, "the group consisting of", the claim reads "the group of consisting of".

c. In claim 19, instead of stating "the non-ionic hydrophilic polymer", the claim reads "the non-hydrophilic polymer". The claim is treated herein as requiring a non-ionic hydrophilic polymer.

d. As currently written, claim 33 depends upon itself. The claim is treated herein as dependent upon claim 32. Additionally, cycloalkanes do not include carbon-carbon double bonds, and thus do not belong in this group.

e. In claim 35, the monomer must meet the limitation of claim 34 that it contains a polymerizable carbon-carbon double bond, and cycloalkanes do not meet this limitation.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claim 7 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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The language in lines 3 and 4 of the claim, "sufficient hydrophilicity for liquid to enter the part once having passed the entrance of the part" is considered indefinite because:

- a. A hydrophilic or hydrophobic liquid would be able to enter a hydrophilic structure, depending on other considerations.
- b. How is this liquid defined as having "passed the entrance of the part"? Has it flowed into the part to some degree, or flowed past the entrance on the surface or in a connecting channel?
- c. What would cause the liquid to enter the part? Capillary action, electrokinetic force, hydrodynamic force?

6. Claim 30 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The method as claimed comprises one or more of the listed steps, but:

- a. The detection step requires that the step of running the assay reaction has been performed.
- b. All steps would be required in order for the method to be an analytical assay as stated in the preamble. (i.e. simply preparing a sample is not an assay)

The claim is treated herein as requiring the performance of all three steps.

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7. Claim 37 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The phrase "excluded for use as sole capillaries in capillary electrophoresis" is considered indefinite, because:

- a. By "excluded for use", does the applicant intend that the channels/capillaries cannot be used as "sole capillaries" (i.e. excluded from use) or are they separated (excluded) for the purpose of being used as "sole capillaries"?
- b. The definition of "sole capillaries" is not understood. Are they capillaries that are separated from each other (i.e. no fluid communication between them), or are they capillary tubes as opposed to channels in a microfluidic chip?

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

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9. Claims 1-6, 8, 10, 11, 18-23, 28, 31-36, and 38-41 are rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Amigo.

Addressing claim 1, Amigo discloses a microfluidic device (Column 6, line 46 - Column 8, line 21) comprising a set of one or more (Column 7, lines 29-34) covered microchannel structures (Column 7, lines 49-55) manufactured in the surface of a planar substrate (Column 3, line 36 - Column 4, line 9), wherein non-specific adsorption and hydrophilicity are optimized by a coat exposing a non-ionic hydrophilic polymer on a part of the surface of at least one of the microchannel structures. (Column 4, line 53 - Column 5, line 48) Also regarding the question of optimization, generally, differences in concentration (i.e. in this case, density, thickness, or other variable of the coating) or temperature will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955).

Addressing claim 2, Amigo discloses the surface carrying the coat being made of organic material. (Column 3, line 36 - Column 4, line 22)

Addressing claim 3, Amigo discloses the surface of the planar substrate being made of plastic. (Column 4, lines 10-22)

Addressing claims 4 and 20, Amigo discloses the non-ionic hydrophilic polymer being attached to a polymer skeleton that is attached to the surface. (Column 4, lines 10-64)

Addressing claim 5, Amigo discloses the device comprising more than five covered microchannel structures. (Column 7, lines 29-31)

Addressing claim 6, Amigo discloses microchannel structures that comprise conduits for liquid transport. (Column 4, line 65 - Column 5, line 3)

Addressing claim 8, Amigo discloses microchannel structures comprising a microcavity having a volume less than or equal to 1 μL . (Column 6, line 60 - Column 7, line 14; usual microchannel dimensions give a volume range of 0.02 - 2.5 μL)

Addressing claim 10, Amigo discloses the device being a round disk. (Column 7, lines 20-25)

Addressing claim 11, Amigo discloses the hydrophilic polymer comprising amide or ethylene oxy groups. (Column 5, lines 32-40)

Addressing claims 18 and 19, Amigo discloses the hydrophilic polymer comprising a plurality of amide groups, and being a polymerisate of monomers of acrylamide (i.e. polyacrylamide). (Column 5, lines 32-40)

Addressing claim 21, Amigo discloses covalent attachment between the hydrophilic polymer and the skeleton. (Column 4, lines 59-64)

Addressing claims 22 and 23, Amigo discloses the polymer skeleton being an organic polymer that is neutral. (Column 4, lines 32-40)

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Addressing claim 28, Amigo discloses the surface of the planar substrate being made of a plastic that comprises a non-significant fluorescence for excitation wavelengths in the interval of 200-800 nm and emission wavelengths in the interval of 400-900 nm. (Column 3, line 36 - Column 4, line 9)

Addressing claim 31, Amigo discloses a microfluidic device (Column 6, line 46 - Column 8, line 21) comprising a set of one or more (Column 7, lines 29-34) covered microchannel structures (Column 7, lines 49-55) manufactured in the surface of a planar substrate (Column 3, line 36 - Column 4, line 9), wherein a part of the surface of at least one of the microchannel structures comprises a coat exposing a non-ionic hydrophilic polymer (Column 4, line 53 - Column 5, line 48), and the surface of the planar substrate is made of a plastic that comprises a non-significant fluorescence for excitation wavelengths in the interval of 200-800 nm and emission wavelengths in the interval of 400-900 nm. (Column 3, line 36 - Column 4, line 9)

Addressing claims 32, 34, and 38, Amigo discloses the plastic substrate being based on a polymer of aliphatic monomers containing polymerizable carbon-carbon double bonds. (Column 3, lines 49-54)

Addressing claims 33, 35, and 39, Amigo discloses the monomer being ethylene or propylene. (i.e. product is polyethylene or polypropylene; Column 3, lines 49-54)

Addressing claim 36, Amigo discloses mass transport of solutes and/or particles between different functional parts of the microchannel structure using electroendoosmosis (i.e. electroosmotic flow, EOF). (Column 4, line 65 - Column 5, line 16; Column 6, lines 21-45)

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Addressing claim 40, Amigo discloses the use of a coating of non-ionic hydrophilic polymer to modify the degree of non-specific adsorption and hydrophilicity within a microchannel. (Column 4, line 53 - Column 5, line 48) Regarding the question of optimization, generally, differences in concentration (i.e. in this case, density, thickness, or other variable of the coating) or temperature will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955).

Addressing claim 41, Amigo discloses microchannel structures that comprise conduits for liquid transport. (Column 4, line 65 - Column 5, line 3)

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

11. Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Amigo in view of the provided English translation of DE 197 53 847 (Zimmer et al).

Amigo discloses a device as described above in addressing claim 1.

Amigo does not explicitly disclose the surface having a sufficient hydrophilicity for liquid to enter the part once having passed the entrance of the part. (i.e. by capillary forces)

Zimmer et al disclose the ability of capillaries with sufficiently hydrophilic surfaces, including polymer surfaces, to draw in aqueous materials upon contact.
(Pages 5-8)

It would have been obvious to one having ordinary skill in the art to modify the device of Amigo by providing a surface of sufficient hydrophilicity at a channel opening to draw aqueous fluids in by capillarity, as taught by Zimmer et al, because it would facilitate sample introduction in some applications. (e.g. biosensor)

12. Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Amigo in view of Regnier et al.

Amigo discloses a device as described above in addressing claim 1.

Amigo does not explicitly disclose mass transport of solutes or particles between different functional parts of a microchannel structure using a liquid flow caused by non-electrokinetic forces.

Regnier et al disclose bulk fluid motion caused by non-electrokinetic means.
(Column 37, lines 53-59)

It would have been obvious to one having ordinary skill in the art to modify the device of Amigo by using a non-electrokinetic means of moving fluid within the channels, as taught by Regnier et al, because it would prevent electrophoretic bias in

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the injection procedure. Additionally, if the object of the application of the hydrophilic coating was to minimize or substantially eliminate electroosmotic flow (See Amigo, Column 5, lines 9-16), then a non-electrokinetic means of bulk fluid motion would be required in order to have efficient fluid flow.

13. Claims 12, 13, and 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Amigo in view of Karger et al.

Amigo discloses a device as described in addressing claims 1 and 11 above.

Amigo does not explicitly disclose a device comprising a polyhydroxy hydrophilic polymer (Claim 12), a polyhydroxy polymer selected from among polysaccharides, polyvinyl alcohols, and poly(hydroxyl alkyl vinyl ether) polymers (Claim 13), or the device being in a dry state that is capable of being rehydrated. (Claim 29)

Karger et al disclose the use of a polyvinyl alcohol coating in electrophoresis capillaries in order to minimize adsorption of analytes to the capillary walls and control electroosmosis. (Column 1, line 50 - Column 2, line 39) (Claims 12 and 13) They also disclose the subsequent drying of the coated capillaries (Column 7, lines 1-39), and the rehydrating of the capillaries in later analyses. (Column 7, line 40 - Column 8, line 43) (Claim 29)

Addressing claims 12 and 13, it would have been obvious to one having ordinary skill in the art to modify the invention of Amigo by replacing his non-ionic hydrophilic coating with the polyvinyl alcohol coating taught by Karger et al, because Karger et al

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teach that it performs similar functions, and it would possess different reactivity that could facilitate a particular analysis.

Addressing claim 29, it would have been obvious to one having ordinary skill in the art to modify the invention of Amigo by providing the device in a dry state that is capable of being rehydrated, as taught by Karger et al, because it would facilitate device storage and shipping.

14. Claims 14 and 24-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Amigo in view of Bergstrom et al. (US 5,250,613)

Amigo discloses a device as described in addressing claims 1 and 20 above.

Amigo does not explicitly disclose use of a hydrophilic polymer that is a reaction product between ethylene oxide and a dihydroxy or a polyhydroxy compound. (Claim 14) Amigo also does not explicitly disclose the use of a polyamine skeleton (Claim 24), a polyethylene imine skeleton (Claim 25), or a skeleton with a molecular weight of 10,000 - 3,000,000 Da. (Claim 26)

Relevant to claim 14, Bergstrom et al disclose the use of a coating of an adduct of ethylene oxide and a dihydroxy or polyhydroxy compound as a hydrophilic polymer that prevents or reduces analyte adsorption to a surface. (Column 7, lines 20-24; Column 1, line 56 - Column 2, line 28)

Relevant to claims 24-26, Bergstrom et al disclose the use of a polyethylene imine skeleton with molecular weight of 10,000 - 1,000,000 Da. (Column 3, lines 15-49; Column 7, lines 41-52) Polyethylene imine is a polyamine.

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Addressing claim 14, it would have been obvious to one having ordinary skill in the art to modify the invention of Amigo by replacing his non-ionic hydrophilic coating with a coating of an adduct of ethylene oxide with dihydroxy or polyhydroxy compounds, as taught by Bergstrom et al, because Bergstrom et al teach that it performs similar functions, and it would possess different reactivity that could facilitate a particular analysis.

Addressing claims 24-26, it would have been obvious to one having ordinary skill in the art to modify the invention of Amigo by replacing his non-ionic hydrophilic coating with a biopolymer (e.g. cellulose, starch) coating supported by a skeleton of polyethylene imine with a molecular weight of 10,000 - 1,000,000, as taught by Bergstrom et al, because Bergstrom et al teach that it performs similar functions, and it would possess different reactivity that could facilitate a particular analysis.

15. Claims 15-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Amigo in view of Malmsten et al.

Amigo discloses a device as described in addressing claim 11 above.

Amigo does not explicitly disclose use of a polymer comprising one or more blocks of polyoxyethylene chains (Claim 15), the use of polyethylene glycol as the hydrophilic polymer (Claim 16), or the use of polyethylene glycol with a methoxy group at the end that does not bind to the surface as the hydrophilic polymer. (Claim 17)

Malmsten et al disclose the use of polyethylene glycol as a hydrophilic coating for minimizing protein adsorption in biological applications. (Abstract, Introduction) A

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variety of polyethylene glycol was disclosed that had methoxy end groups that do not bind the surface (Tables 2 and 3, Pages 512-515)

It would have been obvious to one having ordinary skill in the art to modify the invention of Amigo by replacing his non-ionic hydrophilic coating with the polyethylene glycol coating taught by Malmsten et al, because Malmsten et al teach that it performs similar functions, and it would possess different reactivity that could facilitate a particular analysis.

16. Claims 1 and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Karger et al in view of Van Alstine.

Relevant to claim 1, Karger et al disclose a microfluidic device (Column 2, lines 27-32) comprising a set of one or more covered microchannel structures (Column 9, line 18 - Column 10, line 4) manufactured in the surface of a planar substrate (Column 2, lines 27-32), wherein non-specific adsorption and hydrophilicity are altered by a coat exposing a non-ionic hydrophilic polymer on a part of the surface of at least one of the microchannel structures. (Column 2, lines 20-39)

Relevant to claim 27, Karger et al disclose the substrate being made of plastic (Column 6, lines 15-22), and preparation of a bare capillary surface (silica) with acid to ensure proper surface functionalization for the coating reaction. (Column 7, lines 1-11)

Karger et al do not explicitly disclose the part surface without coat being hydrophilized by a plasma treatment or oxidation agent in order to introduce functional groups that allow for a subsequent attachment of a coat onto the part surface.

Relevant to claim 27, Van Allstine discloses the preparation of a plastic substrate for coating by plasma treatment, in order to introduce reactive surface groups. (Column 6, lines 14-21 and 31-39)

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device of Karger et al by preparing the plastic substrate for coating by plasma treatment, as taught by Van Allstine et al, because it would provide a dry, less labor-intensive means of surface preparation.

Also regarding the question of optimization, generally, differences in concentration (i.e. in this case, density, thickness, or other variable of the coating) or temperature will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955).

17. Claims 1 and 30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Regnier et al in view of Amigo.

Relevant to claim 1, Regnier et al disclose a microfluidic device (Column 35, line 6 - Column 36, line 53) comprising a set of one or more (Column 35, lines 53-59) covered microchannel structures (Column 36, lines 10-13) manufactured in the surface of a planar substrate (Figures 8 and 10), wherein non-specific adsorption and hydrophilicity are affected by a coat exposing a non-ionic hydrophilic polymer on a part

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of the surface of at least one of the microchannel structures. (Column 37, lines 12-29, especially line 27)

Relevant to claim 30, Regnier et al disclose a method of performing an analytical assay (Example 2) comprising preparing a sample (Column 42, lines 63-65); running an assay reaction (Column 42, line 65 - Column 43, line 7), and detecting the result of the assay reaction, wherein the result is a measure of the activity of the sample. (Column 43, lines 12-20)

Regnier et al do not explicitly disclose optimization of non-specific adsorption and hydrophilicity by the coat of the non-ionic hydrophilic polymer.

Amigo discloses the optimization of non-specific adsorption in conjunction with hydrophilicity in a device using the same and similar coatings (e.g. polyacrylamide) (Column 4, line 65 - Column 5, line 40) Also regarding the question of optimization, generally, differences in concentration (i.e. in this case, density, thickness, or other variable of the coating) or temperature will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the invention of Regnier et al by optimizing non-specific adsorption and hydrophilicity by the coat of the non-ionic hydrophilic polymer, as taught by Amigo, because it would reduce sample loss.

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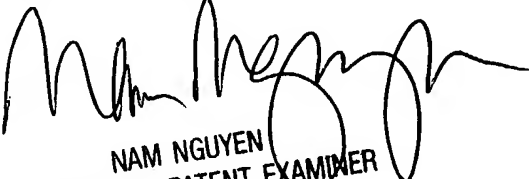
Conclusion

18. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dr. Jeffrey Barton, whose telephone number is (571) 272-1307. The examiner can normally be reached Monday-Friday from 8:30 am – 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nam Nguyen, can be reached at (571) 272-1342. The fax number for the organization where this application or proceeding is assigned is (703) 872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at (866) 217-9197 (toll-free).

JTB
September 9, 2004


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